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10/501,202

07/09/2004

Henryk Struszczyk

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

07/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/501,202

Applicant(s)

STRUSZCZYK ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicant's amendment and response filed one May 16, 2007 have been received and entered into the case. Claims 16 – 39 are canceled; claims 1 – 15 are pending and have been considered on the merits. All arguments have been fully considered.

### ***Claim Rejections - 35 USC § 112***

Rejections under 35 U.S.C. 112, second paragraph, are withdrawn due to amendment.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6 – 10 and 14 – 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Masanori (01-185301).

Applicant claims a method for preparing a modified microcrystalline chitosan, the method comprising degrading chitosan in an aqueous, acidic solution to achieve a desired molecular weight wherein the solution has a concentration of at least about 0.001% chitosan; alkalizing the acidic solution under vigorous agitation, with an aqueous base to form a second

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solution having about 0.01 – 20% chitosan and a pH of about 7; and precipitating the microcrystalline chitosan from the solution. The degrading step uses a hydrolytic agent selected from hydrochloric acid or chloroacetic acid; the chitosan has a final concentration in the acidic solution of 0.1 – 2%; the acidic solution comprises an acid selected from acetic acid, lactic acid, citric acid, and hydrochloric acid; and has a pH 6.9 or less; the alkalizing step uses a base selected from sodium hydroxide, potassium hydroxide and ammonium hydroxide; and the method occurs at 20C or higher, or 40 – 80C.

Masanori teaches a method for modifying chitosan, the method comprising dissolving (degrading) chitosan in an acidic solution; then adding an alkali, specifically sodium hydroxide) to obtain a 0.5 – 10% chitosan solution with a pH of 7 – 12 (abstract). The chitosan is precipitated out with H<sub>2</sub>O<sub>2</sub> (abstract). The acid may be acetic acid, hydrochloric acid, the temperature is 40 – 90C (abstract).

The reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 3 and 12 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kazutsume in view of Masanori.

Applicant claims a method for preparing a modified microcrystalline chitosan, the method comprising degrading chitosan in an aqueous, acidic solution to achieve a desired molecular weight wherein the solution has a concentration of at least about 0.001% chitosan; alkalizing the acidic solution under vigorous agitation, with an aqueous base to form a second solution having about 0.01 – 20% chitosan and a pH of about 7; and precipitating the microcrystalline chitosan from the solution. The degrading step uses an enzyme selected from cellulose, chitinase, and xylanase; and is carried out at 20C or higher, or 30 – 60C.

Kazutsume teaches a method for modifying chitosan, the method comprising combining chitosan and chitosanase (or degrading with chitinase) followed by adding sodium hydroxide (an alkali) and precipitating out the chitosan (abstract).

Kazutsume does not teach the method wherein the degrading step is carried out at 20C or higher, or 30 – 60C. However, Masanori teaches a method for modifying chitosan wherein the method degraded chitosan followed by adding an alkali wherein the method occurs at 40 – 90C. As evidenced by Masanori, it was well known in the art to modify chitosan at the instant

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temperatures. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice to practice the method of Kazutsume in the claimed temperature ranges as it was a recognized temperature for such methods.

6. Claims 1 and 4 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawamura et al. (US 483323).

Applicant claims a method for preparing a modified microcrystalline chitosan, the method comprising degrading chitosan in an aqueous, acidic solution to achieve a desired molecular weight wherein the solution has a concentration of at least about 0.001% chitosan; alkalizing the acidic solution under vigorous agitation, with an aqueous base to form a second solution having about 0.01 – 20% chitosan and a pH of about 7; and precipitating the microcrystalline chitosan from the solution. The degrading step uses an oxidative agent selected from hydrogen peroxide and sodium perborate; the degrading step uses a hydrolytic agent selected from hydrochloric acid or chloroacetic acid; the chitosan has a final concentration in the acidic solution of 0.1 – 2%; the acidic solution comprises an acid selected from acetic acid, lactic acid, citric acid, and hydrochloric acid; and has a pH 6.9 or less; the alkalizing step uses a base selected from sodium hydroxide, potassium hydroxide and ammonium hydroxide; or a base selected from sodium carbonate, potassium carbonate and ammonium carbonate.

Kawamura teaches a method for modifying chitosan, the method comprising dissolving (degrading) chitosan in an aqueous acidic solution, followed by adding an alkali (abstract) and precipitating the chitosan. Specifically, acetic acid or chloroacetic acid is used (col.2 line 48-55), or alternatively sodium perborate (col.2 line 65-68). The alkali used in the method may be

sodium hydroxide, potassium hydroxide, sodium carbonate or potassium carbonate (cool.3, line 15-35).

The reference does not teach the method wherein the pH is specifically 7, or wherein the claimed amounts of chitosan are obtained. However, the reference clearly identifies the solution is basic, or alkaline. Thus, it would have been obvious to one of ordinary skill in the art to make the solution to a pH of at least 7 in following the teaching so Kawamura. In addition, at the time of the claimed invention, the chitosan was recognized as the desired final product, thus one in the art would have been motivated to optimize the amount of product obtained in following the methods. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of chitosan obtained in the final solution, with a reasonable expectation for successfully obtaining a modified chitosan.

### ***Response to Arguments***

Applicant argues that the references do not teach each of the claimed elements, in that they do not teach making a microcrystalline chitosan; they do not teach degrading in acid solution; they do not teach vigorous agitation with alkaline; and they do not precipitate out the chitosan.

However, these arguments fail to persuade because Masanori and Kawamura specifically teaches the same steps as claimed, thus while it does not teach the microcrystalline structure, it must inherently have the same structure. Furthermore, Masanori teaches degrading in acid (abstract), which meets the limitations of the claim.

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Regarding the degrading, the references clearly teach degrading in acid or chitinase.

Regarding the vigorous agitation, it is noted that such a term is relative and subjective in nature. Thus, stirring as disclosed by the references may include the claimed agitation.

Finally, it is noted that the references clearly teach precipitating with water or filtering (also a method for precipitating).

For these reasons the claims stand rejected.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/  
Primary Examiner  
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July 20, 2007